



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/030,650	03/25/87	DAVISON	590-7022

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EXAMINER	
EXAMINER	
ART UNIT	PAPER NUMBER
121	4

DATE MAILED: 10/06/87

This is a communication from the examiner in charge of your application  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENTS ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                  |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449       | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474      | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-12 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-12 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheets of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved, ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☒ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received  
\_\_\_\_\_ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1955 C.D. 11; 453 O.G. 213.
14. ☐ Other \_\_\_\_\_

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Art Unit 121

Receipt is acknowledged of papers submitted under 35 U.S.C. 119, which papers have been placed of record in the file.

Claims 2-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Composition claims should recite an amount of active ingredient to be used, either in actual amounts or in functional language.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 12 is rejected under 35 U.S.C. 101 because product claims cannot be drafted in terms of use.

Clinical Products Ltd. v. Brenner, Commr of Pats., 149 USPQ 475.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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Art Unit 121

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-12 are rejected under 35 U.S.C. 103 as being unpatentable over Campbell et al in view of Schmidt et al and optionally in view of Spiegel et al.

The claims are drawn to the besylate form of amlodipine and compositions containing the same.

Campbell et al disclose amlodipine. See page 1 of the instant specification.

Schmidt et al disclose that aryl sulfonic acid salts of basic nitrogen containing pharmaceuticals are preferred over other salts. See the "background of the invention", where the Campbell preferred maleates are specifically disclosed to be inferior to the aryl sulfonic acid salts.

One of ordinary skill would find the instantly claimed besylate of amlodipine to be prima facie obvious for the Campbell disclosure, modified as taught by Schmidt.

Spiegel et al is an example of a pharmaceutical wherein the besylate form is specifically identified to be the preferred embodiment. See column 2, line 39.

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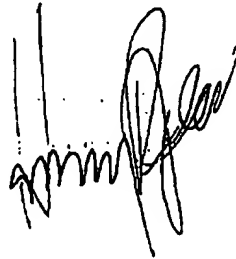
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One of ordinary skill would particularly find the besylate form to be obvious in view of the Spiegel disclosure.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-3920.

  
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557-3645  
10/5/87



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